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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,583	12/14/2005	Katherine Ann Vousden	2543-1-041PCT/US	4893
23565	7590	10/22/2007		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER OGUNBIYI, OLUWATOSIN A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 10/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 10/537,583	Applicant(s) VOUSDEN, KATHERINE ANN	
	Examiner Oluwatosin Ogunbiyi	Art Unit 1645	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 21 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1 and 8.  
Claim(s) withdrawn from consideration: 14-16 and 18-22.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**ROBERT A. ZEMAN**  
**PRIMARY EXAMINER**

### **ADVISORY ACTION**

The amendment filed on 9/21/07, under 37 CFR 1.116, in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because, minimally, the proposed amendment introduces new limitations that have not been previously considered and would require new considerations.

### **Claim Rejections Maintained**

#### **35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since applicant's arguments are predicated on an amendment not of record, said arguments are deemed non-persuasive. Consequently, this rejection is maintained for the reasons of record and is reiterated below.

The claim is drawn a method of screening or testing for candidate anti-fungal compounds that impair *Candida albicans* ATP (CTP): tRNA nucleotidyltransferase enzyme (CCA1) activity comprising:

a) providing a *C. albicans* cell wherein the cell expresses *Candida albicans* ATP (CTP): tRNA nucleotidyltransferase enzyme (CCA1) under the control of a heterologous promoter

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- (b) providing one or more candidate compounds;
- c) contacting said *Candida albicans* cell(s) with said one or more candidate compounds;
- d) inducing said promoter;
- e) determining the effect of the candidate compound on activity by assessing the effect on growth or viability of said cells; and
- f) comparing said activity to the activity of a sample of the *C. albicans* cell(s) wherein said promoter is repressed.

The nature of the invention as set forth supra involves screening or testing for an anti-fungal compound that impairs *C. albicans* CCA1 by determining the effect of said compound on growth or viability of *C. albicans* cells expressing *C. albicans* CCA1.

The specification on p.2 line 38 teaches that CCA1 is an essential protein for the fungal species *Candida*. Example 4 on p. 10 gives a demonstration of CCA1 as an essential gene product in *Candida albicans*. A *Candida albicans* strain with one copy of the CCA1 gene under the control of tetracycline inducible promoter expresses CCA1 under strong induction i.e. without tetracycline and does not express CCA1 under tight repression i.e. with tetracycline. Under CCA1 expression, there is cell growth and no significant growth was observed when CCA1 is repressed (p. 11 example 4.2).

However, this in vivo assay system for screening or testing for an anti-fungal compound that impairs *C. albicans* CCA1 and that described in the claim does not take into account that there are more than one essential genes in *C. albicans* (Song et al. Microbiology (2003), 149:219-259, Veses et al. Eukaryotic Cell (2005), p. 1088-1101, Bruno et al. Trends in Microbiology (2004) 12: 157-161, p.159, table 2) and also a compound may have multiple targets including CCA1. The claim requires contacting a candidate compound with a *Candida albicans* cell(s) expressing CCA1. If negative effects on growth or viability are seen in said cell(s), how does one of skill in the art determine that said negative effect is due to impairment of CCA1 by the candidate compound? The specification and the claim does not correlate impairment of growth or viability with the direct impairment with CCA1. The assay described in the specification

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and claim does not provide any guidance or direction as to how to rule out the effects of such compound on other essential genes in said *C. albicans* expressing CCA1.

For example, Onishi et al (Feb. 2000, Antimicrobial Agents and Chemotherapy p. 368-377 cited in previous action.) teaches a screen for in vitro antifungal activity of several compounds by a growth inhibition assay (page 369 column 1 materials and methods and table 1) and then the compounds were evaluated to determine whether said compounds were direct inhibitors of the enzyme by measuring the enzyme's activity in the presence of said compounds (page 370 column 2 first full paragraph, page 373 column 1 - 2 and table 4).

Assessing inhibition of growth does not provide any knowledge about the effect of the compound on CCA1 activity as claimed because as mentioned above a compound may have more than one target in said *C. albicans* expressing CCA1 including CCA1. Furthermore, an anti-fungal compound has many different activities (see Ghannoum et al. 1999. Clinical Microbiology Reviews, p. 501-517 for different mode of actions of some anti-fungal compounds, cited in previous office action) and these compounds would inhibit growth but do not have to impair activity of CCA1. As such, impairment of growth is not directly correlated with impairment of CCA1 activity in the method of screening set forth in the claim. One of skill would not reasonably conclude from the claim that a compound that impairs CCA1 activity is solely responsible for impairing growth in a *C. albicans* cell expressing *C. albicans* CCA1.

In view of the above, it would require undue experimentation for the skilled artisan to use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Since applicant's arguments are predicated on an amendment not of record, said arguments are deemed non-persuasive. Consequently, this rejection is maintained for the reasons of record and is reiterated below.

The claim is drawn to a method of screening or testing for candidate anti-fungal compounds that impair *Candida albicans* ATP(CTP):tRNA nucleotidyltransferase enzyme (CCA1) activity comprising:

- a) providing fungal *Candida albicans* CCA 1;
- b) providing one or more candidate compounds;
- c) contacting said CCA 1 with said one or more candidate compounds; and
- d) determining the interaction of the candidate compound with said activity of CCA 1.

Step (d) as recited in the claim is confusing. The recitation of *determining the interaction of a candidate compound with said activity of CCA1* is unclear. Can a compound interact with activity? Since the preamble of the claim is a *method of screening or testing for candidate anti-fungal compounds that impair Candida albicans ATP(CTP):tRNA nucleotidyltransferase enzyme (CCA1) activity*, it is suggested that Applicant amend step (d) to recite *determining the ability of the candidate compound to inhibit CCA1 activity*.

### **Status of Claims**

Claims 1 and 8 are rejected. Claims 14-16 and 18-22 are withdrawn.

### **Conclusion**

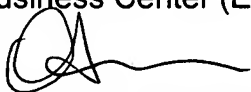
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 4:00 pm. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Bruce Campell can be reached on 571-272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Oluwatosin Ogunbiyi

Examiner

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ROBERT A. ZEMAN  
PRIMARY EXAMINER